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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,102	06/20/2000	Christopher Graham Raphael Parsons	MERZ30 / dln	6038

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,102	PARSONS ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's request for continued examination (RCE) filed April 19, 2004, and response filed August 30, 2004 and amendment filed June 17, 2004 wherein claims 1-13 and 15-17 have been amended; claim 14 is cancelled previously.

Currently, claims 1-13 and 15-17 are pending in this application.

Claims 1-13 and 15-17 are examined on the merits herein.

Note that Applicant's amendment filed June 17, 2004 has been entered and under examination herein. An oversight on this amendment in the previous Office Action June 29, 2004 is regretted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. (WO 99/01416, of record) in view of Greenshaw A J ("*Behavioural pharmacology of 5-HT3 receptor antagonists: a critical update on therapeutic potential*", PTO-892), and Ravelli et al. (of record) or Sullivan et al. (of record) or Wilde et al.(of record).

Gold et al. discloses that administering the same 1-aminoalkylcyclohexanes compounds as herein in combination with one or more pharmaceutically-acceptable diluents, excipients, or carriers to a living animal including a human (see page 29 line 26 to page 30 line 12), are useful in a pharmaceutical composition and method for treating, eliminating, and alleviating CNS disorders (see page 3 lines 17-20) or a living animal for alleviation of a condition which is alleviated by an NMDA receptor antagonist. Gold et al. also disclose a method of manufacture of the instant claimed compounds. See abstract, pages 4-8, 10-20, and claims 1-34 of Gold et al.

Thus, Gold et al. teaches broad usefulness of the instant compounds in methods of the treatment of pathological conditions such as CNS disorders.

Note that Gold et al. discloses the effective amounts of the compound herein in the range of 20 mg to 100 mg/day or 10 mg to 250 mg/day, or 1-1000 mg/day or 50-500 mg/day (see page 29 lines 18-22, page 30 line 5-6), which are within or same as the effective amounts 1-1000 mg/day or 1-500 mg/day, indicated in Applicant's specification (see page 22 the last four lines of the specification).

Gold et al. does not expressly disclose the employment of the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal.

Greenshaw discloses that 5-HT3 receptor antagonists since their discovery and the subsequent identification of 5-HT3 receptors in the CNS are potentially useful in the treatment of nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, dementia and drug abuse.

Ravelli et al. teaches that vomiting, also as known emesis is a known and common disorder of the central nervous system (CNS) in a patient. See abstract and entire article.

Sullivan et al. teaches that appetite disorders are known disorders of the central nervous system (CNS) in a patient. See abstract and entire article.

Wilde et al. teaches that cerebellar tremor are known disorders of the central nervous system (CNS) in a patient. See abstract and entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the same active compounds of the formula herein in methods of treating of the particular disorders or conditions such as emesis, cerebellar tremor, or appetite in a living animal, since the same active compounds are known to be useful in a method of treating CNS disorders broadly according to Gold et al. It is known that emesis, cerebellar tremor, or appetite is CNS-related disorders according to the prior art. It is also known that 5-HT3 receptor antagonists since their discovery and the subsequent identification of 5-HT3 receptors in the CNS are useful in the treatment of CNS disorders such as nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, dementia according to Greenshaw

Thus, the CNS disorders, taught by Gold et al. would encompass emesis, cerebellar tremor, appetite , nausea, inflammatory pain (migraine and irritable bowel syndrome), anxiety, depression, schizophrenia, and dementia. Therefore, the patient population in Gold et al. is deemed to encompass the patient herein suffering emesis, cerebellar tremor, appetite or inflammatory pain (migraine and irritable bowel syndrome).

Therefore, one of ordinary skill in the art would have reasonably expected that the same active compounds of the formula herein, would have beneficial therapeutic effects and usefulness in methods of the particular CNS disorder, emesis, cerebellar tremor, appetite or inflammatory pain (migraine and irritable bowel syndrome) in a patient, by administering the same effective amounts of the same compound of Gold et al.

Applicant's arguments filed August 30, 2004 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been considered but are moot in view of the new ground(s) of rejection above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 15-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 7 of copending Application No. 10/288,819 being allowed for the same reasons of record stated in the previous Office Action dated June 29, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same method-of-treating a living animal for alleviation of a condition treatable by a 5HT3 antagonist selected from the group consisting of anxiety disorders, depressive disorders, Schizophrenia and treatment related psychosis, drug and alcohol abuse disorders, cognitive disorders, Alzheimer's disease, Parkinson's disease, cerebellar tremor, migraine, appetite disorders, inflammatory bowel syndrome (1BS), and emesis, comprising the step of administering to the living animal an amount of the same compound, as the instant claimed method.

Thus, the copending Application No. 10/288,819 and the instant claims are deemed to substantially overlap.

Thus, the instant claims 1-13 and 15-17 are deemed to anticipate the claims 5 and 7 of copending Application No. 10/288,819.

Response to Argument

Applicant's arguments filed August 30, 2004 with respect to the obviousness-type double patenting rejection of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant asserts that "US Serial No. 10/288,819 does not involve the same compounds as the instant application". Contrary to Applicant's assertion, the compound in US Serial No. 10/288,819 does indeed involve the same compounds as the instant application, i.e., when U-V-W-X-Y-Z is cyclohexane, and R* is the same, so are the other substituens. Thus, the compounds of formula I in claim 7 are deemed to encompass the instant compounds.

Therefor, the instant claims 1-13 and 15-17 are deemed to anticipate the claims 5 and 7 of copending Application No. 10/288,819.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
November 16, 2004